

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS NOTICE

35-11

7/7/11

VERIFICATION ACTIVITIES RELATED TO THE USE OF INGREDIENTS OF PUBLIC HEALTH CONCERN

I. PURPOSE

This notice instructs inspection program personnel (IPP) to make establishments aware of the need for them to have appropriate process controls for ingredients of public health concern, the need for the ingredients to be properly labeled, and the importance of taking steps to prevent the production and shipment into commerce of adulterated or misbranded meat, poultry, or egg products. This notice is necessary because of a sustained number of adulterated and misbranded meat and poultry products recalled because of the presence of undeclared ingredients, especially ingredients of public health concern, specifically allergens.

II. BACKGROUND

A. The consumption of meat, poultry, and egg products containing these undeclared ingredients, often one of the “big eight” allergens (see Paragraph C below), may result in adverse health reactions. The total numbers of meat and poultry recalls in 2009 and 2010 associated with undeclared allergens are 14 and 18, respectively. In the first half of 2011, there have been 27 recalls for undeclared ingredients; 20 of which were because of undeclared allergens. These recalls for undeclared allergens reflect potential public health hazards.

B. Many of these recalls occurred as a result of a change in product formulation by the establishment or a change in a supplier’s ingredient formulation that was not reflected on the labeling of the finished meat or poultry product in which the ingredient was used. For example, several products, such as barbecue beef, kippered turkey, and seasoned pork loins, were the subject of recalls because of undeclared ingredients, including soy, whey (a milk derived ingredient), and wheat. These allergens are food safety hazards that should be considered in the establishment’s hazard analysis. The occurrence of a recall due to undeclared ingredients indicates that an establishment has failed to

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address the chemical (allergen) food safety hazard in its hazard analysis, failed to support the decision in the hazard analysis, failed to reassess the hazard analysis, or failed to effectively implement the controls to support the decision (see 9 CFR 417.2, 417.3, 417.4, 417.5, 417.8). Awareness by IPP of the consequences of undeclared ingredients is critical for protecting public health.

NOTE: Although there have been no recalls of egg product due to the presence of undeclared ingredients of public health concern reported, such ingredients may, nonetheless, be found in these products. To prevent the possibility of such an event occurring and to prevent adverse health reactions associated with the consumption of undeclared allergens in egg products, IPP in egg products plants are also to conduct an awareness meeting with plant management, following the instructions in this notice.

C. IPP need to be aware that the consumption of certain food ingredients, even when present at very low levels, has been associated with adverse reactions, such as food allergies and intolerances. Eight categories of foods, i.e., the “big eight,” are associated with food allergies, which are adverse immunological reactions in sensitive individuals due to the protein in these foods. Situations involving the non-declaration of the “big eight” allergens can result in a Class I or Class II recall (refer to FSIS Directive 8080.1 for additional information on the recall of meat and poultry products). Other potential causes of adverse reactions in sensitive individuals are attributed to ingredients such as sulfites, lactose (a sugar found in milk), gluten, and Yellow 5 (tartrazine).

NOTE: The “big eight” allergens are: *wheat, Crustacean shellfish (e.g., shrimp, crab, lobster), eggs, fish, peanuts, milk, tree nuts (e.g., almonds, pecans, walnuts), and soybeans. These allergens cause approximately 90 percent of all food allergy reactions.*

III. INSPECTION PROGRAM PERSONNEL RESPONSIBILITIES

A. At the weekly meeting with establishment management following issuance of this notice, IPP are to discuss the following:

1. The rising public health concern related to the use and labeling of meat, poultry and egg products with ingredients of public health concern, especially the “big eight” allergens. Refer to the example under section II.B.
2. Recent recalls of meat and poultry products with undeclared ingredients of public health concern (e.g., wheat, soy, and milk). Additional information on specific recalls can be found at:
http://www.fsis.usda.gov/Fsis_Recalls/Open_Federal_Cases/index.asp

B. IPP are also to inform the establishment that controls it may consider include measures that:

1. Address the potential for incorrectly formulating or mislabeling such as ensuring that a supplier's ingredient statement has not changed without notice;
2. Ensure that the appropriate label is applied to each product;
3. Ensure that the product is manufactured in accordance with the product formula in the labeling record; and
4. Ensure that effective sanitation measures are in place to address the potential for cross-contamination when formulating multiple products with different formulations (e.g., prerequisite program, targeted Sanitation SOP procedures).

Attention to these matters will limit the possibility of failing to declare an ingredient of public health concern and of any other ingredient or formulation error.

C. For meat and poultry establishments, IPP are to discuss the adequacy of current decision-making documentation to support the decision in the hazard analysis when addressing the chemical food safety hazard, 9 CFR 417.5(a)(1).

D. Additionally, IPP are to inform establishments that within 30 days of the issuance of this notice FSIS intends to issue a second Notice that provides instructions to IPP to verify that product formulations containing any of the "big eight" allergens are consistent with the ingredients statement on the approved labels. That notice will instruct IPP to verify the control procedures an establishment uses when it changes suppliers, or when a supplier's formulation changes (e.g., when a seasoning blend is updated with new ingredients or when a product formulated by the establishment is changed), to ensure that all ingredients are fully disclosed.

E. IPP are to document the meeting in a memorandum of interview (MOI), as specified in FSIS Directive 5000.1 and FSIS PHIS Directive 5000.1. At a minimum, the MOI is to include a list of participants in the meeting and document the discussion between IPP and establishment management associated with controls to support the decision in the hazard analysis when addressing the chemical (allergen) food safety hazard. The MOI is to be kept in the inspection file, with a copy provided to establishment management.

Refer questions regarding this notice to the Policy Development Division through askFSIS at <http://askfsis.custhelp.com> or by telephone at 1-800-233-3935. Questions specific to FSIS' labeling requirements for ingredients should be directed to the Labeling and Program Delivery Division through askFSIS using the above web-link or by telephone at 301-504-0878.

A handwritten signature in black ink, appearing to read "Daniel J. Segal". The signature is fluid and cursive, with a large initial "D" and "S".

Assistant Administrator
Office of Policy and Program Development